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SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/166,925 12/14/93 FALCK-PEDERSEN

E 19603230

EXAMINER

CAMPBELL, B

18M2/0821

ART UNIT

PAPER NUMBER

9

SUSAN J. TIMIAN
NIXON, HARGRAVE, DEVANS & DOYLE
CLINTON SQUARE TOWER
P.O. BOX 1051
ROCHESTER, NEW YORK 14602

1804

DATE MAILED: 08/21/95

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined *for restriction only* ☐ Responsive to communication filed on _____ ☐ This action is made final.

A shortened statutory period for response to this action is set to expire _____ month(s) _____ days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- | | |
|---|---|
| 1. <input type="checkbox"/> Notice of References Cited by Examiner, PTO-892. | 2. <input type="checkbox"/> Notice of Draftsman's Patent Drawing Review, PTO-948. |
| 3. <input type="checkbox"/> Notice of Art Cited by Applicant, PTO-1449. | 4. <input type="checkbox"/> Notice of Informal Patent Application, PTO-152. |
| 5. <input type="checkbox"/> Information on How to Effect Drawing Changes, PTO-1474. | 6. <input type="checkbox"/> _____ |

Part II SUMMARY OF ACTION

1. ☒ Claims 1-16 are pending in the application.

Of the above, claims _____ are withdrawn from consideration.

2. ☐ Claims _____ have been cancelled.

3. ☐ Claims _____ are allowed.

4. ☐ Claims _____ are rejected.

5. ☐ Claims _____ are objected to.

6. ☒ Claims 1-16 are subject to restriction or election requirement.

7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.

8. ☐ Formal drawings are required in response to this Office action.

9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).

10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____, has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).

11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).

12. ☐ Acknowledgment is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____; filed on _____.

13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.

14. ☐ Other _____

Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-11 and 16, drawn to expression vectors and a method for making same, classified in Class 435, subclass 320.1.

II. Claim 12, drawn to an animal infected with an adenovirus vector, classified in Class 800, subclass 2.

III. Claims 12 and 13, drawn to unicellular hosts transformed with an expression vector, classified in Class 435, subclass 240.2.

IV. Claims 14 and 15, drawn to a method of producing a protein, classified in Class 435, subclass 69.1.

Claim 12 encompasses two distinct inventions, unicellular hosts and multicellular animal hosts. Should either of groups II or III be elected, claim 12 will be examined to the extent that it encompasses the elected subject matter.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the vector of I can be used for gene therapy or vaccination.

Inventions I and each of II and III are related as mutually exclusive species in intermediate-final product relationship. Distinctness is proven for claims in this relationship if the intermediate product is useful to make other than the final product (M.P.E.P. § 806.04(b), 3rd paragraph), and the species are patentably distinct (M.P.E.P. § 806.04(h)).

In the instant case, the intermediate product is deemed to be for production of two different final products, the multicellular animals of II and the unicellular hosts of III, and the inventions are deemed patentably distinct since there is nothing on this record to show them to be obvious variants. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions anticipated by the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

Groups II and III are distinct because they are drawn to two materially different products having different properties and utilities. The animals of II can be used for production of meat, fur or other products, production of antibodies, etc. The cells of III may be used for production of proteins or production of adenovirus particles. Furthermore, different methods are required to produce the animals of II and the cells of III.

Groups II and IV are distinct because the animals of II are not required for the method of IV and the method of IV is not required to produce the animals of II.

Inventions III and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the process of IV, protein production, can be carried out with other commercially available vectors. Alternatively, proteins may also be synthesized chemically or isolated from natural sources.

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Art Unit: 1804

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter restriction for examination purposes as indicated is proper.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruce Campell, whose telephone number is 703-308-4205. The examiner can normally be reached on Monday-Thursday from 8:30 to 5:00 (Eastern time). The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jacqueline Stone, can be reached on 703-308-3153. The FAX phone number for art unit 1804 is 703-308-4312.

An inquiry of a general nature or relating to the status of the application should be directed to the group receptionist whose telephone number is 703-308-0196.

Bruce Campell
August 9, 1995

Bruce Campell

BRUCE R. CAMPBELL
PATENT EXAMINER
GROUP 1804